

COAL TAR CREOSOTE (CASE 0139) PRODUCT SPECIFIC DATA CALL-IN RESPONSE

Explanation for Registrant Response "1" – Data To Be Produced

Explanation for Registrant Response "6" – Data Cited From Existing Study

Explanation for Registrant Response "7" – Waiver Requested Based on the Rationale Provided

Explanation for Registrant Response "8"- Not Applicable for Creosote Based on the Criteria Expressed in the Footnotes

Guideline Number	Study Title	Registrant Response	Rationale
830.1550	Product Identity & Composition	6	MRID: 44802214, 44802215 (Creosote Council III) 44802205, 44802206 (Rutgers)
830.1600	Description of Materials	1	Data To Be Produced
830.1620	Description of Production Process	1	Data To Be Produced
830.1650	Description of Formulation Process	1	Data To Be Produced
830.1670	Discussion of Impurities	1	Data To Be Produced
830.1700	Preliminary Analysis	6	MRID: 44802214, 44802215 (Creosote Council III) 44802205, 44802206 (Rutgers)
830.1750	Certified Limits	1	Data To Be Produced
830.1800	Enforcement Analytical Method	6	MRID: 44784214, 44784215 (Creosote Council III) 44784205, 44784206 (Rutgers)
830.6302	Color	6	MRID: 44784229, 44784230 (Creosote Council III) 44784220, 44784221 (Rutgers)
830.6303	Physical State	6	MRID: 44784229, 44784230 (Creosote Council III) 44784205, 44784206 (Rutgers)

Guideline Number	Study Title	Registrant Response	Rationale
830.6304	Odor	6	MRID: 44784229, 44784230 (Creosote Council III) 44784220, 44784221 (Rutgers)
830.6361	Stability to Normal & Elevated Temperatures	6	MRID: 44784229, 44784230 (Creosote Council III) 44784220, 44784221 (Rutgers)
830.6314	Oxidizing or Reducing Action	8	Rutgers requests a waiver based on the following rationale: DCI footnote 19 requires these data only if the product contains an oxidizing or reducing agent. Creosote is not an oxidizing or reducing agent and does not contain oxidizing or reducing agents.
830.6315	Flammability	8	Rutgers requests a waiver based on the following rationale: DCI footnote 20 requires these data only if the product contains combustible liquids. The flash point for creosote is >200°F (PMCC) giving it an NFPA flammability rating of 1, meaning slightly combustible.
830.6316	Explodability	8	Rutgers requests a waiver based on the following rationale: DCI footnote 21 requires these data only if the product is potentially explosive. Creosote is only slightly combustible and is not potentially explosive.
830.6317	Storage Stability	6	MRID: 45355601, 45355602 (Creosote Council III) 45355801, 45355802 (Rutgers)
830.6319	Miscibility	8	Rutgers requests a waiver based on the following rationale: DCI footnote 22 requires these data only if the product is an emulsifiable liquid and is to be diluted with petroleum solvents. Creosote is not an emulsifiable liquid.
830.6320	Corrosion Characteristics	6	MRID: 45355601, 45355602 (Creosote Council III) 45355801, 45355802 (Rutgers)
830.6321	Dielectric Breakdown	8	Rutgers requests a waiver based on the following rationale: DCI footnote 23 requires these data if the end use product is a liquid and is used around electrical equipment. Creosote is a liquid but is used only to pressure treat wood. As a liquid, creosote does not come into contact with electrical equipment. It is not an "insulating liquid" as described in OCSPP testing guideline 830.6321 for Dielectric Breakdown Voltage.
830.7000	pH	8	Rutgers requests a waiver based on the following rationale: DCI footnote 25 requires these data only if the product is dispersible with water. Creosote is not dispersible with water.

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830.7050	UV/Vis Absorption	7	Rutgers requests a waiver because as defined by EPA in the OCSSP Test Guideline 830.7050, UV/Visible Absorption is a function of the molar extinction coefficient of the test substance, which, in turn, is expressed as moles/liter. Since creosote is a complex mixture of mixed and variable composition, there is no molecular weight representative of creosote and, therefore, no means to express a molar extinction coefficient and no means to quantify absorption. However, as EPA indicates in its OCSSP Test Guideline 830.7050, the absence of measureable absorption does not preclude the possibility of photodegradation. Creosote contains predominantly polyaromatic hydrocarbon structures. These aromatic structures all contain chromophobic structures and are typified by benzo(a)pyrene, for example, which, according to the National Library of Medicine Toxicology Data Base "contains chromophores that absorb at wavelengths >290 nm and therefore is expected to be susceptible to direct photolysis by sunlight" (http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~B42s5R:1). Since the primary purpose of UV/Vis Absorption 830.7050 testing is to measure ultraviolet/visible light absorption to obtain an indication of the wavelengths at which the test compound may be susceptible to photodegradation in the atmosphere, testing for UV/Vis absorption is unnecessary for creosote.
830.7100	Viscosity	6	MRID: 44784229, 44784230 (Creosote Council III) 44784220, 44784221 (Rutgers)
830.7200	Melting Point	8	Rutgers requests a waiver based on the following rationale: DCI footnote 28 requires these data only if the product is a solid at room temperature. Creosote is a liquid at room temperature.
830.7220	Boiling Point	6	MRID: 44784214, 44784215 (Creosote Council III) 44784205, 44784206 (Rutgers)
830.7300	Density	6	MRID: 44784214, 44784215 (Creosote Council III) 44784205, 44784206 (Rutgers)
830.7370	Dissociation Constant in Water	8	Rutgers requests a waiver based on the following rationale: DCI footnote 34 requires these data only if the product contains an acid or base functionality or an alcoholic functionality. Based on Preliminary Analysis data, the phenol and phenolic content of creosote is 0.1% or less.

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830.7550	Partition Coefficient: Shake Flask	6	MRID: 44784229, 44784230 (Creosote Council III) 44784220, 44784221 (Rutgers)
830.7560	Partition Coefficient: Generator Column	7	Rutgers requests a waiver because results from partition coefficient tests would be questionable if not uninterpretable. Creosote, a complex mixture of mixed and variable composition, contains more than 145 identified compounds. No compound is present at a concentration greater than 12.5% and only 7 compounds are present at concentrations of 1% or greater. The general theoretical basis for partition testing and the analytical component rely on quantitative analysis for specific compounds dispersed between two solvents. According to EPA test guidelines for partition coefficient testing (830.7550), the Nernst partition law "strictly applies to a pure substance dispersed between two pure solvents". EPA test guidelines also state that the possibility that more than one solute can occur in one or both phases at the same time may affect the results. This possibility is unavoidable in partition testing of a mixture as complex as creosote, and as a consequence, quantitation of creosote in the water or the organic phase would be no more than a crude estimate.
830.7570	Partition Coefficient: LC estimation	7	Rutgers requests a waiver because results from partition coefficient tests would be questionable if not uninterpretable. Creosote, a complex mixture of mixed and variable composition, contains more than 145 identified compounds. No compound is present at a concentration greater than 12.5% and only 7 compounds are present at concentrations of 1% or greater. The general theoretical basis for partition testing and the analytical component rely on quantitative analysis for specific compounds dispersed between two solvents. According to EPA test guidelines for partition coefficient testing (830.7550), the Nernst partition law "strictly applies to a pure substance dispersed between two pure solvents". EPA test guidelines also state that the possibility that more than one solute can occur in one or both phases at the same time may affect the results. This possibility is unavoidable in partition testing of a mixture as complex as creosote, and as a consequence, quantitation of creosote in the water or the organic phase would be no more than a crude estimate

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830.7840	Water Solubility: Column Elution, Shake flask	8	Rutgers requests a waiver based on the following rationale: DCI footnote 37 requires that if the TGAI cannot be isolated data are required on the practical equivalent of the TGAI (the salt or ester of the acid, base or ionic form of the TGAI). The TGAI of creosote cannot be isolated and does not form a salt or ester. Creosote, a complex mixture of mixed and variable composition, contains more than 145 identified compounds. No compound is present at a concentration greater than 12.5% and only 7 compounds are present at concentrations of 1% or greater. Results from water solubility testing would be questionable if not uninterpretable.
830.7860	Water Solubility: Generator Column	8	Rutgers requests a waiver based on the following rationale: DCI footnote 38 requires that if the TGAI cannot be isolated data are required on the practical equivalent of the TGAI (the salt or ester of the acid, base or ionic form of the TGAI). The TGAI of creosote cannot be isolated and does not form a salt or ester. Creosote, a complex mixture of mixed and variable composition, contains more than 145 identified compounds. No compound is present at a concentration greater than 12.5% and only 7 compounds are present at concentrations of 1% or greater. Results from water solubility testing would be questionable if not uninterpretable.
830.7950	Vapor Pressure	6	MRID: 44784229, 44784230 (Creosote Council III) 44784220, 44784221 (Rutgers)
870.1100	Acute Oral Toxicity	6	MRID: 43032101, 43032301 The end use product is not diluted for use. Testing for acute oral toxicity was conducted on the product as formulated for sale and distribution.
870.1200	Acute Dermal Toxicity	6	MRID: 43032102, 43032302 Testing for acute dermal toxicity was conducted on the product as formulated for sale and distribution.
870.1300	Acute Inhalation Toxicity	6	MRID: 43032103, 43032303 Testing for acute inhalation toxicity was conducted on the product as formulated for sale and distribution.
870.2500	Acute Dermal Irritation	6	MRID: 43032105, 43032305 Testing for acute dermal irritation was conducted on the product as formulated for sale and distribution.

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Guideline Number	Study Title	Registrant Response	Rationale
870.2600	Skin Sensitization	6	MRID: 43675301, 43675201 Testing for skin sensitization was conducted on the product as formulated for sale and distribution.
870.2400	Acute Eye Irritation	6	MRID: 43032104, 43032304 Testing for acute eye irritation was conducted on the product as formulated for sale and distribution.

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